



Docket No. ORT-1643-US-NP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Sui et. al.

Serial No. : 10/612,138

Art Unit: 1614

Filed : July 2, 2003

Examiner: Not yet assigned

For : NOVEL ESTRIENO [3,2-b]/[3,4-C]PYRROLE DERIVATIVES
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(Name of applicant, assignee, or Registered Representative)



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Commissioner for Patents
P.O. Box 1450
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FIRST INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached);
or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached);
or
☐ Please charge Deposit Account No. 10-
0750/ / the fee of \$180.00 as set forth in
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☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because

this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

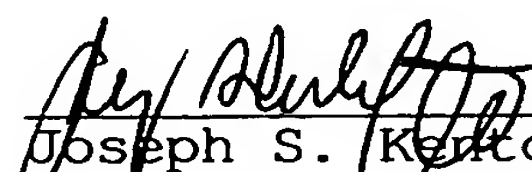
☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1643-US-NP/JSK. This form is submitted in triplicate.

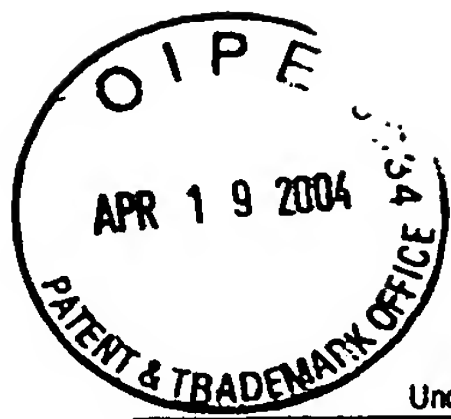
Respectfully submitted,



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DATED: 4/14/04



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	10/612,138
Filing Date	July 2, 2003
First Named Inventor	Zhihua, S.
Group Art Unit	1614
Examiner Name	Not yet assigned
Attorney Docket Number	ORT-1643 US NP

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code ² (if known)			
		6,262,270		Draper et al.	07-17-2001	
		6,133,288		Grese	10-17-2000	
		6,004,971		Grese	12-21-1999	
		5,726,186		Grese	03-10-1998	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵				
		WO	97/09044		Eli Lilly and Co.	03-13-1997		
		WO	01/01969		Endoresherche, Inc.	01-11-2001		
		EP	0761669		Eli Lilly and Co.	11-22-2000		

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
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Sheet 2 of 2

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Group Art Unit	1614
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Attorney Docket Number	ORT-1643 US NP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		CLINTON, R.O. et al.: "Communications to the Editor. Steroidal [2,3-d]isoxazoles". Journal of Organic Chemistry, January (1961), 26, page 279. Sterling-Winthrop Research Institute, New York.	
		HIRSCHMANN, R. et al.: "Communications to the Editor. Synthesis and Structure of Steroidal 4-Pregнено[3,2-c] Pyrazoles. A Novel Class of Potent Anti-Inflammatory Steroids". Journal of American Chemical Society, (1963), 85, pages 120-122. Merck Sharp & Dohme, New Jersey.	
		CLINTON, R.O. et al.: "Communications to the Editor. Steroidal [3,2-c]Pyrazoles". Journal of American Chemical Society, (1959), 81, pages 1513-1514. Sterling-Winthrop Research Institute, New York.	
		ACKERMAN, J.H. et al.: "Steroidal Heterocycles. X. Steroidal[3,2d]pyrimidines and Related Compounds". Sterling-Winthrop Research Institute, New York, Journal of Medical Chemistry, Vol.7, (1964), pgs. 238-240.	
		ALBERT, J.L. et al.: "Estrogen Regulation of Placental Alkaline Phosphatase Gene Expression in a Human Endometrial Adenocarcinoma Cell Line". Cancer Research, (50), pgs. 3306-3310, June 1, 1990.	
		Allan, G.F. et al.: "An Ultrahigh-Throughput Screening Assay for Estrogen Receptor Ligands". Analytical Biochemistry Vol. 275, pgs. 243-247, (1999).	
		CLINTON, R.O. et al.: "Steroidal[3,2-c]pyrazoles. II. Androstanes, 19-Norandrostanes and their Unsaturated Analogs". Journal of American Chemical Society, (1961), 83, pgs. 1478-1491. Sterling Winthrop Research Institute, New York.	
		GUPTA, R. et al.: "Synthesis and Biological Activity of Azasteroidal [3,2-c] and [17,16-c]pyrazoles". European Journal of Medical Chemistry, (1996), 31, pgs. 241-247.	
		HIRSCHMANN, R. et al.: "Synthesis and Structure of Steroidal Pregn-4-eno-and 5 a-Pregnano [3,2-c]pyrazoles. A Novel class of Potent Anti-Inflammatory Steroids". Journal of American Chemical Society, (1964), 86, pgs. 1520-1527.	
		LAITONJAM, W.S. et al.: "Synthesis of some A- and D-ring Fused Steroidal Pyrazoles, Isoxazoles and Pyrimidines". Steroids (2002), 67, pgs. 203-209.	
		MANSON, A.J. et al.: "Steroidal Heterocycles. VII. Androstano[2,3-d]isoxazoles and Related Compounds" Journal of Medicinal Chemistry (1963) 6, no.1, pgs. 1-9.	
		RADU, I. et al.: "New Efficient Pathway for the Synthesis of 3-Aminoestrone", Tetrahedron Letters (2002), 43, pgs. 7617-7619.	
		ROTTLANDER, M. et al.: "Palladium-Catalyzed Cross-Coupling Reactions with Aryl Nonaflates: A Practical Alternative to Aryl Triflates" (1998), 63, pgs. 203-208.	
		WEIDNER, J.J. et al.: "Preparation of N-Aryl-2-hydroxypropionamides from Hydroxy Aromatic Compounds Using a One-Pot Smiles Rearrangement Procedure." Tetrahedron, (1997), 53, no.18, pgs.6303-6312.	
		WELSHONS, W.V.: "Stimulation of breast cancer cells in vitro by the environmental estrogen enterolactone and the phytoestrogen equol". Breast Cancer Research and Treatment 10, (1987), pgs. 169-175.	
		ALBERT, J.L.: "Estrogen Regulation of Placental Alkaline Phosphatase Gene Expression in a Human Endometrial Adenocarcinoma Cell Line". Cancer Research 50, (1990) pgs. 3306-3310.	
		ALLAN, G.F.: "An Ultrahigh-Throughput Screening Assay for Estrogen Receptor Ligands". Analytical Biochemistry 275 (1999), pgs. 243-247.	
Examiner Signature		Date Considered	

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